

**UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF DELAWARE**

ABBOTT LABORATORIES, an Illinois
corporation,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC., a
Delaware corporation,

Defendant.

Case No. CV-07C-00250***

Magistrate Judge Mary Pat Thyng

**ABBOTT LABORATORIES' REPLY TO
TEVA'S FIRST AMENDED COUNTERCLAIM**

Plaintiff Abbott Laboratories ("Abbott"), by and through its undersigned counsel, hereby
replies to the counterclaim of Defendant Teva Pharmaceuticals USA, Inc. ("Teva"):

THE PARTIES

1. Teva USA is a Delaware corporation, having its principal place of business at
1090 Horsham Rd., P.O. Box 1090, North Wales, Pennsylvania 19454.

RESPONSE: Upon information and belief, admitted.

2. Upon information and belief, and according to the Complaint, Abbott is an Illinois
corporation, having its principal place of business at Abbott Park, Illinois 60064.

RESPONSE: Admitted.

JURISDICTION AND VENUE

3. This counterclaim arises under the patent laws of the United States, Title 35,
United States Code, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the food
and drug laws of the United States, 21 U.S.C. § 355.

RESPONSE: The allegations contained in paragraph 3 constitute legal conclusions to
which no response is required. To the extent that a response is required, Abbott admits that Teva

purports to state a counterclaim arising under the various statutes cited in paragraph 3, but denies that this counterclaim has any merit.

4. Jurisdiction in this Court is proper under 28 U.S.C. §§ 1331, 1332, 1338, 2201, and 2002, and the patent laws of the United States, Title 35, United States Code.

RESPONSE: The allegations contained in paragraph 4 constitute legal conclusions to which no response is required. To the extent that a response is required, Abbott admits that the Court has subject-matter jurisdiction over Teva's counterclaim, but denies that this counterclaim has any merit.

5. Venue in this Court is proper under 28 U.S.C. § 1391.

RESPONSE: The allegations contained in paragraph 5 constitute legal conclusions to which no response is required. To the extent that a response is required, Abbott admits that this District is a proper venue to adjudicate Teva's counterclaim, but denies that this counterclaim has any merit.

BACKGROUND FACTS

6. Teva USA reasserts and incorporates by reference the allegations contained in Paragraphs 1-5 of its Counterclaims.

RESPONSE: Abbott incorporates and restates each of its responses to paragraphs 1 through 5 of the counterclaim as if fully set forth herein.

7. Abbott holds an approved New Drug Application ("NDA") from the FDA for a divalproex formulation that sells under the name DEPAKOTE® ER.

RESPONSE: Admitted.

8. NDA holders or applicants are required to file with the FDA the patent number and expiration information for any patent that claims the drug that is the subject of the NDA and any patent that claims a method of using the subject drug. These patents are then published in the FDA's Orange Book.

RESPONSE: Abbott admits that applicants are required to comply with 21 U.S.C. § 355(b)(1)(G), which states that "[t]he applicant shall file with the application the patent

number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” Abbott further admits that the FDA compiles a reference book called the “Orange Book,” which lists any patent reported under § 355(b)(1)(G) to the FDA. Abbott denies all remaining allegations in paragraph 8.

9. In connection with the NDA for DEPAKOTE® ER, Abbott has caused nine patents to be listed by the FDA in the Orange Book: United States Patent Nos. 4,913,906, 4,988,731, 5,212,326, 6,419,953, 6,511,678, 6,528,090, 6,528,091, 6,713,086, and 6,720,004 (the “Listed Patents”).

RESPONSE: Abbott admits that United States Patent Nos. 4,913,906; 4,988,731; 5,212,326; 6,419,953; 6,511,678; 6,528,090; 6,528,091; 6,713,086; and 6,720,004 are listed in the FDA Orange Book in connection with the 500 mg strength of Depakote® ER. Abbott denies all remaining allegations in paragraph 9.

10. On or about March 20, 2007, Teva USA gave notice to Abbott that it had filed ANDA No. 78-700 with the FDA, seeking the FDA’s approval to manufacture, use, and sell its proposed divalproex sodium extended release tablets, equivalent to 500 mg valproic acid (hereinafter, “Teva USA’s divalproex product”). Teva USA provided a Paragraph IV certification as to six of the Listed Patents: United States Patent Nos. 6,419,953, 6,511,678, 6,528,090, 6,528,091, 6,713,086, and 6,720,004 (the “Certified Patents”). Abbott brought suit against Teva asserting only one of the Certified Patents - the ‘953 patent.

RESPONSE: Abbott admits that on or about March 20, 2007, Teva gave notice to Abbott that Teva had filed ANDA No. 78-700 with the FDA, which, on information and belief, seeks the FDA’s approval to manufacture, use, and/or sell Teva’s divalproex sodium product. Abbott lacks knowledge or information sufficient to form a belief as to whether Teva’s divalproex sodium product is “equivalent to 500 mg valproic acid,” and therefore denies this assertion. Further responding, Abbott admits that, on or about March 20, 2007, Teva provided Abbott with a Paragraph IV certification as to the Certified Patents, but Abbott denies that the

“Detailed Statement of the Factual and Legal Bases” for Teva’s Paragraph IV certification was either complete or accurate. Abbott admits that, at this time, it has asserted only the ‘953 patent in this action. Abbott denies all remaining allegations in paragraph 10.

11. Teva USA’s divalproex sodium product does not infringe any claim of the ‘953 patent.

RESPONSE: Denied.

COUNT I: DECLARATION OF NON-INFRINGEMENT OF THE ‘953 PATENT

12. Teva USA reasserts and incorporates by reference the allegations contained in Paragraphs 1-11 of its Counterclaims.

RESPONSE: Abbott incorporates and restates each of its responses to paragraphs 1 through 11 as if fully set forth herein.

13. There is an actual, substantial, and continuing judiciable controversy between Teva USA and Abbott regarding the alleged infringement of the ‘953 patent.

RESPONSE: The allegations contained in paragraph 13 constitute legal conclusions to which no response is required. To the extent that a response is required, Abbott admits that this Court has subject-matter jurisdiction to adjudicate Teva’s counterclaim for a declaration of non-infringement of the ‘953 patent, but denies that Teva’s counterclaim has any merit.

14. Neither Teva USA’s divalproex product nor any process nor method for making or using Teva USA’s divalproex product is covered by any valid and enforceable claim of the ‘953 patent.

RESPONSE: Denied.

15. Teva USA seeks, and is entitled to, a declaration that Teva’s divalproex sodium does not infringe any valid and enforceable claim of the ‘953 patent.

RESPONSE: Denied.

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Abbott denies all remaining allegations contained in Teva’s counterclaim that are not specifically admitted above. Abbott respectfully prays that this Court (i) deny Teva any relief;

award Abbott its attorneys' fees under 35 U.S.C § 285; and (iii) award Abbott any further such relief as the Court deems just and appropriate.

Dated: June 22, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2007, a true and correct copy of the foregoing **Abbott Laboratories' Reply to Teva's First Amended Counterclaim** was caused to be served on the following via CM/ECF filing and electronic mail:

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